

**Remarks**

Introduction

Claims 25-38 were pending. By way of this response, the specification has been amended, claims 25-38 have been cancelled without prejudice, and claims 39-45 have been added. The specification has been amended to correct various inadvertent typographical errors. Support for the amendments to the specification and new claims can be found in the application as originally filed (e.g., including examples 22-34), and care has been taken to avoid adding new matter. Accordingly, claims 39-45 are currently pending.

Double Patenting

Claims 25-26 have been rejected under the judicially created doctrine of obviousness type double patenting over claims 1 and 2 of U.S. Patent No. 5,919,665.

Applicant does not concede the correctness of the rejections. However, to advance the prosecution of the above-identified application, claims 25-38 have been cancelled, and claims 39-45 have been added. Applicant submits that the subject matter of present claims 39-45 is not obvious over claims 1 and 2 of U.S. Patent No. 5,919,665 since the claims are directed to compositions which comprise a soluble recombinant botulinum toxin protein that comprises a C-terminal portion of a botulinum toxin type A which includes a botulinum toxin receptor binding domain. Therefore, the soluble recombinant botulinum toxin protein of the present compositions includes a portion effective to bind to botulinum toxin receptors.

Thus, the compositions of the present claims are different and distinct from the fusion proteins and host cells of U.S. Patent No. 5,919,665.

In view of the above, applicant submits the double patenting rejection has been overcome and respectfully requests withdrawal of the rejection.

#### Claim Objections

Claims 25-38 have been objected because claim 25 recites "light chain 25 wherein", and claim 28 recites the phrase "wherein the toxin is in solution".

As indicated above, claims 25-38 have been cancelled. Applicant submits that the present claims, that is claims 39-48, do not include the objected language, and are definite.

In view of the above, applicant submits the claim objections have been overcome and respectfully requests withdrawal of the objections.

#### Rejection Under 35 U.S.C. § 102

Claims 25-38 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Dolly et al. (U.S. Pat. No. 6,203,794) as evidenced by Ledoux (1994).

Applicant traverses the rejections as it relates to the present claims.

Dolly et al. discloses a recombinantly produced botulinum toxin light chain coupled to a native botulinum toxin heavy chain (i.e., a botulinum toxin heavy chain obtained from anaerobic Clostridium botulinum bacteria). In addition, Dolly et al. discloses a fusion protein which comprises a botulinum toxin light chain coupled to a maltose binding protein (MBP).

Dolly et al. does not specifically disclose, teach, or suggest the present invention. For example, Dolly et al. does not specifically disclose, teach, or even suggest a recombinant botulinum toxin protein comprising a C-terminal portion of a heavy chain of a botulinum toxin produced in soluble form in aerobic bacteria and obtained therefrom, let alone a composition comprising such a protein, as recited in the present claims.

As discussed above, Dolly et al. discloses the use of MBP in the formation of a recombinant light chain of a botulinum toxin. The present claims are directed to compositions comprising the C-terminal portion of a heavy chain of a botulinum toxin type A. Thus, applicant submits that the compositions disclosed by Dolly et al. and the presently claimed compositions are different and distinct, one from the other. Thus, applicant submits that Dolly et al. does not specifically disclose, teach, or even suggest each and every element recited in the present claims, and therefore, does not anticipate the present claims.

In addition, applicant submits that the present claims are unobvious from and patentable over Dolly under 35 U.S.C. § 103 since Dolly specifically discloses compositions which comprise a

recombinant light chain and not a recombinant protein which comprises a cell binding domain of a botulinum toxin type A toxin.

In view of the above, applicant submits that the present claims, that is claims 39-45, are not anticipated by, and are unobvious from and patentable over, Dolly under 35 U.S.C. §§ 102 and 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims are not subject to obviousness type double patenting, are in proper form, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 39-45, are allowable, and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below before mailing another Office Action.

Date: \_\_\_\_\_

6/10/05

Respectfully submitted,



Frank J. Uxa  
Registration No. 25,612  
4 Venture, Suite 300  
Irvine, California 92618  
(949) 450-1750  
(949) 450-1764 Facsimile